

<u>Checklist of Required Documentation from Sub-Awardee Institution</u> <u>When ISMMS is the Prime Institution on a NIH Competitive Application</u>

The ISMMS contact person should complete this section and send the	is checklist to your contact at the sub-awardee
institution.	
Project Title:	
Prime Institution Name: <u>Icahn School of Medicine at Mount Sinai (IS</u>	MMS)
ISMMS PI Name:E-Mail Address:	
ISMMS Contact Person Name:E-Mail Add	ress:
Project Period Dates:	
Notice of Funding Opportunity Link:	
Yearly Direct Cost Subaward Budget Amount*:	
Budget Type - PI/Dept can specify type and format by checking appropriate	
For modular grants, must include these items at a minimum: all <u>key</u> per	
initial and entire proposed period of support Initial and Entire Summar	
Deadline for Subawardee to Submit Required Documentation:	
Is the Subaward PI also a Multiple PI (MPI)? Yes No	
(Recommended deadline to submit documentation to the ISMMS co	ntact person by e-mail is at least 10 business
days before NIH deadline.)	
Sub-Awardee Institution	
The sub-awardee institution should complete this portion of the fo	rm and submit the <u>required</u> documents to the
ISMMS contact person.	
Name of Institution	
Is your institution participating in FDP Expanded Clearing House Pilo	_ _
Subaward PI Name: E:M	
Name of Person Completing this Form:E:N	lail Address:
Required Documents	
1. Signed Statement of Intent to Establish a Consortium Agro	eement (SOI)
2. Foreign Subrecipients: Inclusion of SOI clause re: NIH NOT	
3. Certification of Compliance with HHS Financial Conflict of	
8/24/2012**	
4. Statement of Work (SOW)	
5. Budget	
6. Budget Justification - For modular grants, must include justificatio	n for all personnel (e.g., Subaward PI, TBN Post doc,
Consultants, Other Significant Contributors). For non-modular grants, mu	
7. Resources and Facilities	
8. Equipment, if applicable	
9. Biosketches for Senior/Key Personnel including Other Sign	nificant Contributors and Consultants
10. eRA Commons ID for Senior/Key Personnel including Oth	ner Significant Contributors and Consultants
include eRA Commons ID on Biosketch. NIH rejects applications	when an eRA Commons ID is missing.
11. Letters of Support, if applicable	
12. Inclusion Enrollment Report <u>data</u> for projects with huma	in subjects, if applicable
13. For institutions not participating in the FDP Expanded Cl	earing House Pilot, please provide:
Address of Institution (include 9 digit zip code if location is in	•
Address of institution (include 5 digit zip code in location is in	THE OSA
Country Congressional District S	AM UEI
14. F&A Rate Agreement. If "No" is checked to "FDP Clearing	thouse" guestion above, please include
15. Other. Please specify.	

Additional Information

1. Signed Statement of Intent to Establish a Consortium Agreement (SOI)

This document is also commonly referred to as "Subcontracting Letter of Agreement," "Consortium Letter of Intent," and "Letter of Commitment or Intent Signed by the Consortium Participant" among other variations. ISMMS will also accept a "PHS 398 Face Page" signed by an authorizing official in lieu of a Statement of Intent.

The SOI is the official letter signed by the sub-awardee institution's Authorizing Organization Official (AOR) attesting that his/her institution is aware of all applicable Federal regulations and policies and will establish a subaward agreement. ISMMS cannot submit the sponsored project application to the extramural funding agency without the SOI. Failure to obtain a signed SOI will result in the Subawardee being removed from the project.

The actual signing of the subaward agreement by ISMMS and the Subawardee will occur at a later date if the project is funded. This <u>letter</u> does not take the place of the <u>agreement</u>. It is a prerequisite for the submission of the project.

The ISMMS template is available on line here:

Then Go to > Forms > Subaward Statement of Intent Template: ISMMS as the Prime Institution

Many institutions use their own Subaward Statement of Intent form. There is no requirement to use the ISMMS template.

2. Foreign Subrecipients: Inclusion of SOI Clause re: NIH NOT-OD-23-182 Data Access Compliance

In accordance with NIH notice NIH Final Updated Policy Guidance for Subaward/Consortium Written Agreements (NOT-OD-23-182), foreign subaward institutions must provide access to copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report, to the primary recipient with a frequency of no less than once per year, in alignment with the timing requirements for Research Performance Progress Report submission. Such access may be entirely electronic, but will be via a method determined by the Prime Institution.

Foreign subaward institutions must either use <u>Mount Sinai's subward statement of intent (SOI)</u> or include the data access language from the SOI.

3. Certification of Compliance with HHS Financial Conflict of Interest (COI) Rules and Regulations Effective 8/24/2012

Effective 8/24/2012, the NIH issued a revised policy on conflict of interest and mandated that all institutions who receive funds from the NIH either directly or as a subaward must comply with the updated policy. The revised regulations were designed to promote greater objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under NIH grants or cooperative agreements will be free from bias resulting from an investigator's financial conflicts of interest. Complete information is located on this NIH site here.

Click <u>here</u> for the list of COI compliant institutions, entitled "List of Compliant Institutions and Entities" located on the Federal Demonstration Partnership (FDP) website.

a. Compliant and on FDP List

If the institution is compliant and also listed on the FDP list, there is no further action necessary.

b. Compliant and not on FDP List

If the institution is compliant and not listed on the FDP list, the Subawardee AOR must certify that

his/her institution is compliant with the COI regulations. The sub-awardee institution must add a certification clause to their Statement of Intent to Establish a Consortium Agreement***, as follows:

"My institution is compliant with HHS Financial Conflict of Interest (COI) Requirements 42 CFR Part 50, Subpart F, entitled "Responsibility of Applicants for Promoting Objectivity in Research" effective 8/24/12.

c. Compliant under ISMMS Policy

Institutions that are not compliant may choose to become compliant under ISMMS Policy. They will need to take <u>2</u> actions as follows <u>each year of the project</u>:

#1: The sub-awardee institution must add a certification clause to their Statement of Intent to Establish a Consortium Agreement***, as follows:

"My institution agrees to comply with HHS Financial Conflict of Interest (COI) Requirements 42 CFR Part 50, Subpart F, entitled "Responsibility of Applicants for Promoting Objectivity in Research" effective 8/24/12 under ISMMS COI policy. Each investigator, defined as a person responsible for the design, conduct or reporting of research regardless of title or position, shall complete the education presentation and disclosure form. Any potential conflicts shall be managed through a plan formulated by ISMMS."

#2: Each investigator, (see definition in #1 above) must complete the education presentation and disclosure form. Both of these items are included on one form. Once signed, please e-mail it back to the ISMMS contact person. One form is required per investigator. The form is located here: Then go to > Forms > "COI Form for New, Competitive Renewals, and Transfer Applications: For Subawardees Complying with ISMMS Policy". (Choose the "Non-competitive, no cost extension, and supplement applications" form for the appropriate yearly renewal.)

4. Statement of Work (SOW)

This is a description of the work the sub-awardee institution will perform. The SOW will be made part of the legally binding subaward agreement if the project is funded. Also, if funded, please note that the

SOW should be 4,000 characters or less and include information that may be made publicly available to comply with Federal Funding Accountability and Transparency Act (FFATA) requirements since it will be used to populate the "Sub-Award Description" section of http://usaspending.gov. There is no template since it is project specific. The document at a minimum should include the objective or purpose of the sub-awardee institution's participation and a general description of the actions to be performed by the site and the expected results.

10. eRA Commons ID for all senior/key personnel including Other Significant Contributors and Consultants
Please make sure an eRA Commons ID is included on the biosketch for all senior/key personnel including Other Significant
Contributors and Consultants

Beginning with NIH competitive application due dates on or after January 25, 2022, all key personnel must include their eRA Commons ID in the application. **NIH is beginning to issue error messages rather than warnings and will reject the NIH application if eRA Commons IDs are missing for key personnel.**

Subaward institutions must <u>register their organization in eRA Commons</u> and create their own eRA Commons IDs for their key personnel.

What Are the Options for Obtaining an eRA Commons Username (Commons ID) For a Senior/Key Person Who Isn't Affiliated With a Registered Organization? Please refer to the "Option 1" instructions in this NIH link.

Mount Sinai GCO assumes that academic institutions that routinely submit NIH grants will already be registered. However, there is a concern that these institutions may not have signed up all their key personnel (e.g., consultant on their subaward project) with eRA Commons user names. An additional concern is that institutions that do not regularly submit grants will not register their organization.

- * Please include facilities and administrative costs on your budget in addition to the direct costs.
- ** If your institution is listed on this FDP website, ISMMS does not need any further COI certification.
- *** As an alternative, the sub-awardee institution can use the ISMMS SOI template located here: Then go to > Forms > "Subaward Statement of Intent Template: ISMMS as the Prime Institution"

Other Notes:

Refer to <u>SF424 Application Guide</u> for complete information on the NIH requirements.